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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,843	03/31/2000	Barbara A. Gilcrest	0054.1088-015	2644

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HOWREY SIMON ARNOLD & WHITE LLP  
 ATTN: MARGARET P. DROSOS, DIRECTOR OF IP ADMIN  
 2941 FAIRVIEW PARK DR, BOX 7  
 FALLS CHURCH, VA 22042

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/540,843

Applicant(s)

GILCHREST ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/24/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 57, 72, 75-79, 81-83, 85, 86, 88, 89, 94, 95, 98-105, 110-113 is/are allowed.
- 6) ☒ Claim(s) 51, 52, 58, 69, 106 and 107 is/are rejected.
- 7) ☒ Claim(s) 71 and 93 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims pending in the application are 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 51, 52, 57, 58, 69, 71, 72, 75-79, 81-83, 85, 86, 88, 89, 93-95, 98-107 and 110-113.

## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1-11, 13-17, 19-20, 23, 25, 26, 29, 32, 51, 52, 57, 58, 69, 71, 72, 75-79, 81-83, 85, 86, 88, 89, 93-95, 98-107, and 110-113 are pending.

Applicants' traversal and the amendment to the claims in paper filed on 6/24/04 is acknowledged.

### ***Priority***

Applicants' claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the US applications (09/048,927; 08/952,697; 08/467,012) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for SEQ ID NOs: 5 and 11 in claims 2, 7, 8, 14-17, 19, 93, 51, 52, 106, and 107 of this application.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The US applications listed above do not disclose either SEQ ID NOs: 5 or 11.

***Claim Objections***

Claims 71 and 93 are objected to because of the following informalities: the claims have incorrect status identifiers. The claims were amended and the current identifiers recite (previously presented). However, the correct status should be (currently amended). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 52, 58, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52, 58, and 69 recite the limitation "said oligonucleotides". There is insufficient antecedent basis for this limitation in the claim. The claims recite: at least one oligonucleotide.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The intended use (said composition is suitable for medicinal or cosmetic use) of the composition in claims 51 and 106 do not have patentable weight for prior art rejections. See MPEP 2111.02. An intended use does not provide a structural difference between the claimed invention and the prior art.

Claim 51 is rejected under 35 U.S.C. 102(b) as being anticipated by Villeponteau et al. (5,583,016). Villeponteau teaches a composition comprising an oligonucleotide sequence consisting of CUAACCCUAAC (SEQ ID NO: 2). See columns 4-5. SEQ ID NO: 2 is the RNA sequence for a DNA sequence that is 100% identical to applicants' SEQ ID NO: 5. Villeponteau teaches producing the cDNA for the RNA sequence and reagents comprising the oligonucleotide (columns 4-5). In addition, the oligonucleotide sequence taught by Villeponteau would anticipate the claimed oligonucleotides sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence.

Claim 106 is rejected under 35 U.S.C. 102(b) as being anticipated by West et al. (5,686,306). West teaches a composition comprising an oligonucleotide sequence consisting of TTAGGG (SEQ ID NO: 2) and a physiologically acceptable carrier (columns 13, 14, and 19). SEQ ID NO: 2 is 100% identical to applicants' SEQ ID NO: 11. In addition, the oligonucleotide sequence taught by West would anticipate the claimed oligonucleotides sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villeponteau et al. (5,583,016) taken with Akhavan-Tafti (6,020,138).

Villeponteau teaches a composition comprising an oligonucleotide sequence consisting of CUAACCCUAAC (SEQ ID NO: 2). See columns 4-5. SEQ ID NO: 2 is the RNA sequence for a DNA sequence that is 100% identical to applicants' SEQ ID NO: 5. Villeponteau teaches producing the cDNA for the RNA sequence and reagents comprising the oligonucleotide (columns 4-5). In addition, the oligonucleotide sequence taught by Villeponteau would be obvious over the claimed oligonucleotides sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence. However, Villeponteau does not specifically teach the oligonucleotide comprising a 5' phosphate.

However, at the time the invention was made, Akhavan-Tafti teaches a method of synthesizing single or double stranded polynucleotides using an oligonucleotide having a 5' phosphate (abstract and columns 2-3). It has been discovered that a series of short oligonucleotide-5'-phosphates can be simultaneously ligated onto a template-bound primer in a contiguous manner to produce the complementary strand of a template polynucleotide or nucleic acid (column 3). Akhavan-Tafti teaches that the method is useful in a variety of applications, including cloning, preparing labeled polynucleotides for diagnostic use, mutation analysis and screening, gene expression monitoring and sequence analysis (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Villeponteau and Akhavan-Tafti, namely to produce an oligonucleotide consisting of SEQ ID NO: 5, wherein the oligonucleotide comprises a 5' phosphate. One of ordinary skill in the art would have been motivated to produce the oligonucleotide because Akhavan-Tafti teaches that an oligonucleotide having a 5' phosphate can be produced in a large quantity for use in a variety of applications.



Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 106 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over West et al. (5,686,306) taken with Akhavan-Tafti (6,020,138).

West teaches a composition comprising an oligonucleotide sequence consisting of TTAGGG (SEQ ID NO: 2) and a physiologically acceptable carrier (columns 13, 14, and 19). SEQ ID NO: 2 is 100% identical to applicants' SEQ ID NO: 11. In addition, the oligonucleotide sequence taught by West would be obvious over the claimed oligonucleotide sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence. However, West does not specifically teach the oligonucleotide comprising a 5' phosphate.

However, at the time the invention was made, Akhavan-Tafti teaches a method of synthesizing single or double stranded polynucleotides using an oligonucleotide having a 5' phosphate (abstract and columns 2-3). It has been discovered that a series of short oligonucleotide-5'-phosphates can be simultaneously ligated onto a template-bound primer in a contiguous manner to produce the complementary strand of a template polynucleotide or nucleic acid (column 3). Akhavan-Tafti teaches that the method is useful in a variety of applications, including cloning, preparing labeled polynucleotides for diagnostic use, mutation analysis and screening, gene expression monitoring and sequence analysis (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of West and Akhavan-Tafti, namely to produce

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an oligonucleotide consisting of SEQ ID NO: 11, wherein the oligonucleotide comprises a 5' phosphate. One of ordinary skill in the art would have been motivated to produce the oligonucleotide because Akhavan-Tafti teaches that an oligonucleotide having a 5' phosphate can be produced in a large quantity for use in a variety of applications.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Claims 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 57, 72, 75-79, 81-83, 85, 86, 88, 89, 94, 95, 98-105, and 110-113 are in condition for allowance because the claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER